

Energist Ltd Section 5	NeoGen PSR System
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DEC 12 2013

Section 5 – 510(k) Summary (21 CFR 807.92)**Applicant**
Energist Ltd**Manufacturer Address**
2 Park Pavilions, Clos Llyn Cwm, Enterprise Park, Swansea SA6 8QY, UK**Contact Person**
Darren Thomas, Chief Technical Officer
Tel: +44 (0)1792 798768 Fax: +44 (0)1792 790735**Establishment Registration Number**
3007353760**Device Trade Name**
NeoGen PSR System**Device Common Name**
Electrosurgical device**Device Classification**
Electrosurgical cutting and coagulation device and accessories
Class II
Product code: GEI
21 CFR 878.4400**Legally marketed Predicate Devices**
The predicate devices for this
Portrait PSR System, K082197**Intended Use**
The NeoGen PSR system is an electrosurgical device for the treatment of dermatologic conditions including acne scars, actinic keratosis, superficial skin lesions and the treatment of wrinkles and rhytides. The treatment is achieved through controlled heating of the outer layers of the skin so that part or all of the epidermis becomes non-viable and there is controlled thermal modification to the underlying dermis.**Indications for Use**
The NeoGen PSR System is intended for treatment of the following dermatological conditions:

- Treatment of wrinkles and rhytides
- Superficial skin lesions
- Actinic Keratosis
- Viral Papillomata
- Seborrheic Keratosis
- Acne Scars

Device Description & Comparison

The NeoGen System is an electro-surgical device intended for use in dermatological applications by trained and duly qualified medical practitioners in hospitals and clinics. The User should be familiar with the medical literature, complications and hazards associated with the use of light-based and other energy systems in the treatment of facial and non-facial rhytides, acne scars and the removal of skin lesions. It is the responsibility of the user to select appropriate patients, to make a correct diagnosis, to determine the treatment required and the post-operative support required for the patient. It is stressed that some pre- and post-operative treatments for typical laser resurfacing procedures should NOT be applied either in preparation of or following a treatment using NeoGen, as this can lead to increased healing time and increased likelihood of unwanted side effects. Refer to the NeoGen Operators Manual for the Indications for Use and Relative Contraindications.

Treatment is achieved through controlled heating of the outer layers of the skin so that part or all of the epidermis becomes non-viable and there is controlled thermal modification to the underlying dermis. Similar biological changes to those from established laser-based dermatological surgical and skin resurfacing technologies are produced.

A NeoGen PSR system comprises:

NeoGen PSR generator

A mobile unit powered from a 100-120/230 VAC standard wall socket comprising a trolley and a generator section. During installation the generator section is attached to the trolley but may be subsequently removed by the user for easier transportation to a different site. Care must be taken to avoid damage to the handpiece/cable when the generator section is being transported in this way.

Footswitch

This is a single pedal type for activation of the output.

Handpiece/Cable Assembly

The handpiece has a single button on the top of its body for activation of the output. Disassembly of this from the generator requires a tool and is not described in this manual.

Procedure Pack

Comprising one or more disposable nozzles that is connected to the handpiece and which have an integral 'key' that is used by the generator to ensure the nozzle is not used beyond its operational life.

Nitrogen gas cylinder

This is not supplied as part of the NeoGen PSR system. Only medical grade (99.5% purity) nitrogen gas is to be used.

NEOGEN TECHNOLOGY

UHF energy from the Generator converts Nitrogen gas into plasma within the handpiece. The plasma emerges from the nozzle at the distal end of the handpiece and is directed onto the skin to be treated. Rapid heating of the skin occurs as the excited gas gives up energy to the skin.

Through the combination within the handpiece of precisely controlled energy and Nitrogen gas, individual plasma pulses are produced that will give predictable tissue effects. Automatic adjustment of the UHF power level and UHF pulse width to the handpiece

enables control of tissue effects by altering the amount of energy delivered by the plasma to tissue for each pulse. In practice, the energy per pulse is adjustable by the User from 1 to 4 Joules for a standard type nozzle.

The range of treatment energies and associated delivery times available has been determined from pre-clinical, clinical studies and expert opinion as being safe and effective for the intended applications when employed by a dermatologist, plastic surgeon or other suitably qualified user. In particular, the NeoGen System provides a predictable depth of thermal modification so limiting unwanted effects that may result in scarring.

To aid accurate distance from the skin surface, the nozzle is fitted with a 5mm stand-off leg. In practice, no pressure should be applied to the skin when using the stand-off, as this will cause variance of the distance of the nozzle from the skin surface, due to the elasticity of the skin, and could potentially result in an uneven application of energy.

Irrespective of the energy level employed for treatment, the effect is not ablative in that there is not an immediate removal of tissue at the time of application. This retention of the skin surface not only protects against the effects of over treatment but also behaves as a biological dressing to support the healing process over the first 4-5 days following treatment.

Comparison of Technological Characteristics

The NeoGen PSR System has an identical intended use to the predicate system and identical technological characteristics except for modifications to the device user interface and software and outer casing design. These differences do not result in differences in performance or raise new questions of safety and efficacy. The NeoGen PSR System also has the same principles of operation, mode of action and equivalent energy outputs that are used by the Portrait PSR system. Laboratory Validation & Verification utilising calibrated test equipment was undertaken to ensure all design specifications were met and were substantially equivalent to the predicate device. Performance data was provided to demonstrate that the system is capable of providing the outputs necessary to achieve its required treatment parameters.

Performance data was gained through the following tests:

- IEC 60601-1:2005 + CORR.1 (2006) + CORR.2 (2007)
- EN 60601-1:2006 + A11:2011
- IEC60601-2-2:2009 (Fifth Ed)
- Laboratory Validation & Verification

The NeoGen PSR System is therefore concluded to be substantially equivalent to the above named predicate device and minor differences to the systems do not raise additional concerns of safety and efficacy.

System Comparison to Predicate device

	NeoGen PSR system	Portrait PSR System
510(k)	This application	K082197
Displayed Values Precision Energy setting	0.1 Joule	0.1 Joule
Max Output Energy	4J	4J
Treatment Pulse Repetition Rate	1.0 to 2.5 Hz in Repeat Pulse mode. Single Pulse mode selectable by the User.	1.0 to 2.5 Hz in Repeat Pulse mode. Single Pulse mode selectable by the User.

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Pulse Width	Output RF pulse width is varied between 5.2 and 15.4 ms according to the energy to be delivered by each RF pulse.	Output RF pulse width is varied between 5.2 and 15.4 ms
Safety		
Classification	Class 1 (BS EN 60601-1:2006), the Generator requires connection to a Protective Earth.	
Type	Type BF Applied Part	Type BF Applied Part
MDD Class	IIb	IIb.
FDA Regulation Number	21 CFR 878.4400	21 CFR 878.4400
FDA Regulation Name	Electrosurgical cutting and coagulation device and accessories.	Electrosurgical cutting and coagulation device and accessories.
FDA Product Code	GEI	GEI
	FDA Regulatory Class II	FDA Regulatory Class II
Duty Cycle	The system has a duty cycle of 20 seconds on, 10 seconds off, for a maximum of 50 plasma pulses at 2.5Hz	
System Operation Ambient Temperature	10 to 30 °C.	10 to 30 °C.
Relative Humidity	30 to 75%.	30 to 75%.
Atmospheric Pressure	700 to 1060 hPa.	700 to 1060 hPa.
Services		
Power Requirements Voltage (single phase)	100 - 120 / 230 Vrms. 6.5A	100 - 120 / 230 Vrms. 6.5A
Max Current		
AC frequency	50/60 Hz	50/60 Hz
Power Consumption	≤650 VA	≤650 VA
Inlet Fuses	Time Lag 'T' type 250 Vac 20 mm x 5mm UL Approved. Current rating 6.3A. Breaking Capacity 1500A @250VAC	Time Lag 'T' type 250 Vac 20 mm x 5mm UL Approved. Current rating 6.3A. Breaking Capacity 1500A @250VAC
Mains Connection	Detachable power cord to IEC-type Appliance inlet. Mains switch controlled ON/OFF operation	Detachable power cord to IEC-type Appliance inlet. Mains switch controlled ON/OFF operation
Footswitch	60V 5A DC	60V 5A DC
RF Output Frequency	2450 to 2480 MHz, typically 2470 MHz. No sub-harmonics	2450 to 2480 MHz, typically 2470 MHz. No sub-harmonics
Modulation	Pulsed CW (Carrier Wave)	Pulsed CW (Carrier Wave)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Energist Ltd
Mr. Darren Thomas
Chief Technical Officer
2 Park Pavilions, Clos Llyn Cwm
Enterprise Park
Swansea, UNITED KINGDOM SA6 8QY

December 12, 2013

Re: K132754.S001

Trade/Device Name: NeoGen PSR System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 6, 2013
Received: December 3, 2013

Dear Mr. Thomas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/industry/default.htm>.

Sincerely yours,

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Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
For Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132754

Device Name: NeoGen PSR System

Indications for Use:

The NeoGen PSR System is intended for treatment of the following dermatological conditions:

- Treatment of wrinkles and rhytides
- Superficial skin lesions
- Actinic Keratosis
- Viral Papillomata
- Seborrheic Keratosis
- Acne Scars

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen A
Digital signature of Long H. Chen A
Digitally signed by Long H. Chen A
on 12/11/2013 11:46:38 -05'00
for FDA, on Behalf of People, on Behalf of US Government, on Behalf of HHS

for BSA

(Division Sign-off)
Division of Surgical Devices
510(k) Number K132754